REMARKS

Claims 1-47 are pending in the application. Claims 1-2, 5, 10-11, 14-15, 20-21, 24-25, 29-31, 34 and 44 have been amended.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

Claim 1

Claim 1, as amended, recites a computer in signal communication with an at least one transducer assembly, the computer having executable signal processing software with programmed instructions to determine at least one harmonic energy level value associated with the echoes and to calculate a fluid volume contained in the cavity based upon the at least one harmonic energy level value associated with an echo having passed through the fluid.

For example, referring, *e.g.*, to FIG. 9 and paragraph 70 of the application, an embodiment is based on the "non-linearity/attenuation" characteristic in differentiating between fluid media and soft tissue media. A single element transducer is placed in front of the bladder. The transducer generates a wide acoustic beam that is able to enclose the full bladder volume. Depending on the volume of urine contained in the bladder (bladder filling) and thus crossed by the acoustic beam, the amount of harmonic distortion generated in the back of the bladder will change. A radio frequency (RF) backscattered signal might be selected from a region of interest located preferably in the backside of the bladder. The amount of energy comprised in the second harmonic or higher harmonic components of the received RF echo signal can be extracted and correlated to the amount of volume of urine that has been encompassed by the acoustic beam. Since harmonic generation is different in tissue than in fluids, only the volume of urine that has been crossed by the acoustic beam would generate more harmonic energy. When the bladder is empty or below a certain volume level, no harmonic distortion occurs, whereas maximal distortion will be obtained for a full volume.

25315
CUSTOMER NUMBER

DXUC-1-1043ROA1

BLACK LOWE & GRAHAM PLLC
701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

In contrast, Ganguly fails to teach or suggest the limitations of claim 1 as discussed above. Referring, *e.g.*, to FIGS. 1-4 and col. 3, line 58 to col. 4, line 12, a monitoring system 10 for estimating the volume of urine in the bladder includes a transducer 12 that transmits ultrasonic beams into the bladder region of a patient 15. The transducer includes a plurality of piezo-electric elements 13 that are grouped and spaced to produce beams that span each of a plurality of transverse planes 16, which lie within a predetermined region of the bladder 14. The transducer 12 produces at least "NP" beams, with at least N beams spanning each of P transverse planes.

The transducer 12 also receives echoes of the tissue structure encountered by the beams, or what are commonly referred to as "A-lines," and supplies corresponding signals to a transceiver 16. The transceiver 18 amplifies and demodulates these signals in a conventional manner and supplies them to a digitizer 20, which produces corresponding digital signals also in a conventional manner. The digitizer 20 then provides the digital signals to a processor 18 which calculates an estimate of the volume of urine contained in the bladder based on the locations of the bladder walls in each of the planes. As such, Ganguly estimates a urine volume based on the geometry of the bladder. In no manner does Ganguly teach or suggest determining at least one harmonic energy level value associated with echoes from a cavity and calculating a fluid volume contained in the cavity based upon the at least one harmonic energy level value associated with an echo having passed through the fluid as is required by claim 1.

Claims 20, 24 and 44

Claims 20, 24 and 44 are patentable for reasons at least similar to those discussed above with regard to claim 1.

Claims 2-19, 21-23 and 25-43

Claims 2-19, 21-23 and 25-43 are patentable by virtue of at least their respective dependencies from claims 1, 20 and 24.

CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

Claim 1

Chalana fails to supply the teachings missing from Ganguly, namely determining at least one harmonic energy level value associated with the echoes and calculating a fluid volume contained in the cavity based upon the at least one harmonic energy level value associated with an echo having passed through the fluid. Accordingly, claim 1 is patentable for reasons discussed above.

Claims 20, 24 and 44

Claims 20, 24 and 44 are patentable for reasons at least similar to those discussed above with regard to claim 1.

Claims 2-19, 21-23 and 25-43

Claims 2-19, 21-23 and 25-43 are patentable by virtue of at least their respective dependencies from claims 1, 20 and 24.

Claim 45

Claim 45 recites determining boundary information of a cavity from harmonic signals in terms of depth, height, and correction factor, K, and calculating at least one of the volume of the cavity from the boundary information and the fluid volume in the body cavity as a product of depth, height, and correction factor K. Neither Ganguly or Chalana teaches or suggests, and the

BLACK LOWE & GRAHAM PLLC
701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

Examiner fails to allege or point out how Ganguly or Chalana teaches or suggests, the use of a correction factor as recited in claim 45.

Claim 46

Claim 46 is patentable by virtue of at least its dependency from claim 45.

25315
CUSTOMER NUMBER

DXUC-1-1043ROA1

BLACK LOWE & GRAHAM PLLC
701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301

CONCLUSION

Applicants assert that pending claims 1-46 are novel, non-obvious, fully enabled and accordingly in condition for allowance. A Notice of Allowance is therefore earnestly solicited.

If the Examiner has any questions, the Examiner is invited to contact the Applicant's attorney listed below.

Respectfully submitted,

BLACK LOWE & GRAHAM PLLC

/P.G. SCOTT BORN/

P. G. Scott Born
Registration No. 40,523
Direct Dial: 206.957.2491

25315
CUSTOMER NUMBER

BLACK LOWE & GRAHAM PLLC
701 Fifth Avenue, Suite 4800
Seattle, Washington 98104
206.381.3300 • F: 206.381.3301